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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,359

07/15/2004

Domenico Fanara

2004_1045A

8158

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7590

05/28/2008

WENDEROTH, LIND & PONACK, L.L.P.

2033 K STREET N. W.

SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,359	Applicant(s) FANARA ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 10-14 and 23-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-8, 10-14 and 23-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed February 27, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

1) Claims 1-3, 5-8, 10, 12-14 and 35-36 were rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen (US 2004/0028772) in view of Cherukuri et al. (US 4,238,510). The rejection is maintained.

Applicant's Arguments

Applicant has amended the claims to include the specific sugars or polyols useful in the compositions of the instant claims. These include mannitol, xylitol and sorbitol. Applicants argue the references only provide general guidance to a person of skill in the art investigating medicaments with compounds of claimed formula I. A skill artisan may look these references, however, a skilled artisan would also examine references that describe medicaments with compounds of formula I for more particular guidance, in particular EP 0811374. This reference teaches low molecular weight alcohols adversely affects stability of compounds of formula I. Applicant further summarizes preferred embodiments and the alcohols that are to be avoided such as methanol, ethanol, isopropanol and glycerin. Applicant asserts the reference teaches the preferred

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embodiments of the cetirizine medicaments are substantially free of alcohols with molecular weights less than 250, cetirizine reacts with alcohols by esterification and the entire formulation should be free of low molecular weight alcohols. Applicant notes polyols are defined as alcohols. Alcohols with molecular weights of less than 100 should be avoided. A person of skill in the art reading the reference would understand that such a molecular weight cut-off was utilized because the authors were particularly concerned with low molecular weight alcohols used for processing the disclosed formulations. A skilled artisan would also understand alcohols such as mannitol, sorbitol and xylitol would degrade cetirizine. Furthermore a preferred embodiment has no alcohols except for a 3350 MW polyethylene glycol. Therefore the reference is teaching away from using mannitol, sorbitol or xylitol. Thus a person skilled in the art would be dissuaded from using these alcohols. These arguments are not persuasive.

Examiner's Response

Applicant is arguing using a reference not relied on by the rejection. The Examiner has taken the teachings of the reference into account and disagrees with Applicant's assertion that one of skill in the art would not use alcohols such as mannitol, sorbitol or xylitol. The reference teaches throughout its text that alcohols with molecular weights of less than 100 should not be used. By Applicant's own admission, the reference's focus is to avoid alcohols with MW of less than 100. The reference also lists as examples alcohols with MW of less than 100 and does not appear to disclose others with MW of more than 100. The reference also discloses using lactose which has a MW

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of about 342 even though the reference discloses an even more preferred embodiment of the dosage form being free of alcohols having a molecular weight of less than 500, as asserted by Applicant. Therefore it appears the reference's primary concern are alcohols such as volatile alcohols used for processing the dosage forms, which have MW of under 100 and are used as solvents as opposed to sweetening agents. Thus, it does not appear that the reference is necessarily teaching away from using polyols such as mannitol, sorbitol and xylitol. More importantly, EP 0811374 suggest using mannitol in the compositions, see page 6, lines 5-10.

2) Claim 11 was rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen (US 2004/0028772) in view of Cherukuri et al. (US 4,238,510) as applied to claims 1-3, 5-8, 10, 12-14 and 35-36 in further view of Hill (US 5,380,530). The rejection is maintained.

Applicant's Arguments

See Applicant's arguments above.

Examiner's Response

See Examiner's Response above.

3) Claims 23-30 and 32-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,627,234). The rejection is maintained.

Applicant's Arguments

Applicant argues the examiner has used impermissible hindsight in utilizing Johnson. Johnson cites at least 350 active agents. Johnson fails to describe any examples relating to cetirizine or present experimental data relating to cetirizine. Thus, a person skilled in the art would have no reason to choose cetirizine among the 350 active agents described. Also see Applicant's Arguments above.

Examiner's Response

Although Johnson discloses a list of active agents, the reference suggests using cetirizine in the compositions. Applicant has not provided any other reasoning or evidence such as unexpected results to show why using cetirizine in the compositions would not have been obvious to one of skill in the art especially in view of its specific recitation in the reference.

4) Claim 31 was rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,627,234) in view of Hill (US 5,380,530). The rejection is maintained.

Applicant's Arguments

See Applicant's arguments above.

Examiner's Response

See Examiner's Response above.

5) Claims 37-38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,627,234) as applied to claims 23-27, 29-30 and 32-34 in view of Kurihara et al. (US 5,344,659). The rejection is maintained.

Applicant's Arguments

See Applicant's arguments above.

Examiner's Response

See Examiner's Response above.

Claims 1-3, 5-8, 10-14 and 23-38 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612